IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Empower Clinic Services, L.L.C., Plaintiff,

v.

Case No. 4:23-cv-4123

Bio Filling Solutions Inc. f/k/a Bio42 Clinical Filling Solutions, Inc., Hanson Irwin Group LLC, David Teer, Lisa Hudanich, Matthew Ludowig, Marc Hanson, and Jerry Irwin, Defendants.

<u>DEFENDANT MATTHEW LUDOWIG'S RESPONSE TO EMPOWER'S MOTION TO SEAL LUDOWIG'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (DKT. 155) AND REPLY IN SUPPORT OF HIS MOTION FOR LEAVE (DKT. 157)</u>

Defendant Matthew Ludowig ("Ludowig") files this response to Plaintiff Empower Clinic Services, L.L.C. ("Empower")'s Motion to Seal portions of Ludowig's Reply in Support of his Motion for Summary Judgment (Doc. 155) and Reply in Support of his Motion for Leave (Doc. 157)(the "Motion") and shows the Court as follows:

I. SUMMARY OF ARGUMENT

Empower's Motion should be denied, because it seeks to seal non-privileged and non-confidential information in which the public has significant interest. Empower's failure to conduct a document-by-document, line-by-line analysis and weighing of the factors as to why each redaction is necessary dooms their Motion. Nonetheless, Empower has little to no legitimate interest in concealing the information that discusses its illegal operation, particularly since the descriptions are general (similar to what would be included on a privilege log). Empower also has no interest in preventing the public from knowing that Empower breached its Release with Ludowig—as Empower has done with other employees—despite the Release expressly stating the Release is not confidential to the extent that a party needs to enforce the Release's provisions. On the other hand, the public has a significant interest in knowing about Empower's distribution of

thousands of contaminated medications to consumers across the country *each day*¹ and ensuring parties uphold settlement releases. The Court should reject Empower's attempt to continue to conceal its illegal conduct (while it continues to falsely advertise that its drugs are of the highest quality). Accordingly, the Court should deny Empower's Motion.

II. BACKGROUND

As pertinent here, among Ludowig's defenses to Empower's are the following:

- (1) Empower released all claims against Ludowig in a Release that Empower signed with Ludowig mere months before it filed this lawsuit (yet, Empower does not mention the Release anywhere in its three separate complaints). *Compare* Doc. 143-2 with Kodiak Products Co., Inc. v. Deegear, 2015 WL 3523195, at *6 (Tex. App. June 4, 2015) (enforcing release with similar language under similar circumstances).
- (2) Empower does not have confidential or trade secret information (much less interests to support a noncompetition covenant), because Empower engages in illegal compounding practices that put the public at risk of the next compounding pharmacy outbreak. *See Wharton Phys. Svcs.*, *P.A. v. Sign. Gulf Coast Hosp.*, *L.P.*, 2016 WL 192069, at *4 (Tex. App.—Corpus Christi Jan. 14, 2016) (requiring interests worthy of protection to enforce noncompete); *Nacogdoches Heart Clinic*, *P.A. v. Pokala*, 2013 WL 451810, at *4-6 (Tex. App.—Tyler Feb. 6, 2013) (affirming refusal to enforce noncompete in medical field due to public policy concerns); *Peat Marwick Main & Co. v. Haas*, 818 S.W.2d 381, 386 (Tex. 1991) (need for noncompete must outweigh injury likely to

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¹ See Drug Quality and Security Act, Pub. L. 113–54 (Nov. 27, 2013); Drug Quality and Security Act; Congressional Record Vol. 159, No. 131 at H5946–HH5965, https://www.congress.gov/congressional-record/volume-159/issue-131/house-section/article/H5946-2) (explaining the public's interest in compounding pharmacies producing sterile drugs due to the public health outbreak that occurred after a compounding pharmacy's contaminated medications killed over 60 individuals, leading to the enactment of the Drug Quality and Security Act).

public); *Johnson v. Structured Assert Servs.*, *LLC*, 148 S.W.3d 711, 727 (Tex. App.–Dallas 1986) (court may decline to enforce contract injurious to public).²

In fact, contrary to Empower's argument that Ludowig served solely as in-house counsel, Empower demoted Ludowig due to his refusal to be complicit in Empower's intentionally illegal activities. (Doc. 157 at 5.) Ludowig's allegations of Empower's blatant disregard for consumer safety and pharmaceutical regulations are substantiated by a decade's worth of FDA and State Board of Pharmacy findings.³ Supporting Ludowig's position that Empower's disregard for

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² Ludowig cites to case law to support his defenses, because Empower continues to refuse to allow discovery into these defenses by making the bare argument that discovery on these defenses would be "irrelevant."

³ FDA Form 483 to Empower Clinic Services, LLC (Nov. 25, 2015), available online at https://www.fda.gov/media/95350/download; FDA Letter, to Arta Shaun Noorian, Owner, Empower Pharmacy, (May 25, 2017), available online at https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-servicesllc-516718-05252017; FDA Letter to Arta Shaun Noorian, CEO, Empower Pharmacy, (July 22, 2019), available online at https://www.fda.gov/media/130590/download; FDA Form 483 to Empower Clinic Services LLC (Mar. 6, 2020), available online https://www.fda.gov/media/137544/download; FDA Letter to Arta Shaun Noorian, Owner, Empower Pharmacy (Oct. 15, 2021), available online at https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-servicesllc-dba-empower-pharmacy-613792-10152021; FDA Form 483 to Empower Clinic Services, LLC (Aug. 5, 2022), available online at https://www.fda.gov/media/162155/download; FDA Form 483 Empower Clinic Services, LLC (Dec. 1, 2023), available online https://www.fda.gov/media/176194/download; FDA Form 483 to Empower Pharmacy (Aug. 28, 2024), available online at https://www.fda.gov/media/182593/download. Corrected Decision and Order, In the Matter of the Accusation Against Empower Clinic Services, LLC DBA empower Pharmacy, Arta Shaun Noorian, Board of Pharmacy Dep't of Consumer Affairs State of Cal. (Jan. 21:16-18, 18. 2023). 15:11. 25:6–7, and 13-57, available online https://www.pharmacy.ca.gov/enforcement/fy2021/ac207117; Letter from Colorado Dep't of Regulatory Agencies **Empower** Pharmacy to (Sept. 17, https://apps2.colorado.gov/dora/licensing/Lookup/PrintLicenseDetails.aspx?cred=931134&conta ct=992231; Stipulation and Final Agency Order, In the Matter of Disciplinary Proceedings Regarding the Non-Resident Prescription Drug Outlet Registration in the State of Colorado of Registration OSP.0006131, Empower Pharmacy, No. PDO https://apps2.colorado.gov/dora/licensing/Lookup/PrintLicenseDetails.aspx?cred=931134&conta ct=992231; In the Matter of Empower Pharmacy Non-Resident Pharmacy Permit Number: 114339, No. 20-L-0040, Alabama State Board of Pharmacy, (July 28, https://albop.blob.core.windows.net/prod/albopdocuments/2022/7/b2c457218dc341bea0b524427 e01b6487292022.pdf?sv=2024-05-04&spr=https&se=2025-05-

consumer safety is ongoing, the FDA made findings substantiating Ludowig's allegations *after Ludowig moved to amend*. *Compare* Doc. 138 (Ludowig April 18, 2025 Motion for Leave to Amend) *with* FDA, Warning Letter to Empower Clinic Services, LLC dba Empower Pharma (published April 22, 2025), available online at https://www.fda.gov/inspections-compliance-empower-pharma-700962-04022025. In the recent FDA findings, the FDA recommended a complete overhaul of Empower's operations due to Empower's continued production of contaminated medications:

[The] FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

Id. Yet, at Empower CEO Shaun Noorian's deposition on June 17, 2025—less than two months after these damning findings—the CEO testified that he could "not recall" the name of a single employee in Empower's compliance department. What the FDA has yet to uncover, which Ludowig will show at the trial in this matter, is that Empower's disregard for FDA and State Board

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²³T20%3A30%3A24Z&sr=b&sp=r&sig=qtrhbbj3ngYl9zK%2B6z%2FXIVaelp1N1X2mmspjs MLyIuA%3D; Administrative Complaint, State of Florida Dep't of Health v. Empower Clinic Services. LLC, 2023-03021, (June 22, 2023), https://mqa-No. internet.doh.state.fl.us/MQASearchServices/HealthCareProviders/LicenseVerification?LicInd=4 42&ProCde=2210&dba=Empower%20Pharmacy&org=EMPOWER%20CLINIC%20SERVICE S%202C%20LLC; Order, Commonwealth of Pennsylvania Bureau of Professionals and Occupational Affairs v. Empower Pharmacy Registration No. NP000041, No. 20-54-000737 (Mar. https://www.pa.gov/content/dam/copapwp-pagov/en/dos/alerts-and-notices/bpoadisciplinary-actions/2024/2024-March.pdf.

³ FDA, Warning Letter to Empower Clinic Services, LLC dba Empower Pharma (published April 22, 2025), available online at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-services-llc-dba-empower-pharma-700962-04022025

of Pharmacy regulations is not mere oversight—it is intentional disregard for the regulations to try to protect its bottom line for private equity investors. Therefore, Empower's illegal compounding practices result in Empower not having legally protectible trade secrets or confidential information, nor does it have information that should be sealed from the public view.

III. LEGAL STANDARD

Courts "heavily disfavor sealing information placed in the judicial record," because judicial records "belong to the American people" and "the public's right of access to judicial records is a fundamental element of the rule of law." *June Medical Services, L.L.C. v. Phillips*, 22 F.4th 512, 519–20 (5th Cir. 2022) (citations omitted). The rationale for public access is even greater where, as here, the case involves matters of particular public interest—a large pharmaceutical company (Empower) seeking to disparage, harass, and silence an individual (Ludowig) who refused to be complicit in Empower's illegal pharmaceutical practices, which are distributing adulterated medications to thousands of individual consumers each day, even after Ludowig entered into a Release that releases all of the claims at issue in this lawsuit. *Id.* (citing *Shane Grp. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016) ("[T]he greater the public interest in the litigation's subject matter, the greater the showing necessary to overcome the presumption of access."). The Fifth Circuit instructs, "Courts should be *ungenerous* with their discretion to seal judicial records" *Id.*

Thus, the Fifth Circuit requires a rigorous analysis: When sealing judicial records and blocking public access to judicial records, the Court must undertake a "document-by-document, line-by-line balancing of the public's common law right of access against the interests favoring nondisclosure." *June Medical*, 22 F.4th at 521 (remanding where district court bulk sealed documents instead of evaluating documents individually and line by line).

IV. ARGUMENT AND AUTHORITIES

Here, Empower improperly asks the Court to seal portions of filings that reference (1) Ludowig's Release with Empower and (2) Empower's illegal activity. Yet, Empower does not conduct the requisite document-by-document, line-by-line analysis. Therefore, as a matter of blackletter Fifth Circuit law and as further set forth below, Empower fails to meet its burden to show sealing is necessary. *E.g., June Medical Services*, 22 F.4th at 519–20.

A. There is nothing confidential about the Release

The Release should not be sealed, because it is not confidential. The Release expressly states it is not confidential "where necessary to . . . enforce this Release or as may be required by any applicable law, regulation or judicial process." (Doc. 143-2.) Moreover, the only provision that is arguably confidential is the reduced monetary amount Empower paid to Ludowig in exchange for Empower releasing all claims against Ludowig. *See* (Doc. 143-2.) Empower has not explained how any others terms of the Release are even remotely confidential. *See generally*, (Motion.) A simple reading of the Release shows that it is not plausible that third parties could use any information in the Release to harm Empower and gain an unfair competitive advantage in the market place—undermining Empower's COO's credibility that swears under penalty of perjury that the Release is confidential and poses a risk of harm to Empower.⁴

B. No communications set forth in the filings are privileged

As to the purported privileged communications, the filings do not reveal the substance of any privileged communications—the descriptions are akin to what would be on a privilege log.

⁴ The only plausible argument of harm to Empower that the undersigned can imagine is if a third party used the Release to show Empower was similarly not upholding its promises in other releases. While this would arguably "harm" Empower by subjecting it to damages for its calculated pattern of breaching releases, the public interest in upholding releases far outweighs

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any potential harm to Empower.

E.E.O.C. v. BDO USA, LLP, 876 F.3d 690, 696 (5th Cir. 2017) ("simply describing a lawyer's advice as 'legal,' without more, is conclusory and insufficient to carry out the proponent's burden of establishing attorney-client privilege"); Navigant Consulting, Inc. v. Wilkinson, 220 F.R.D. 467, 474 (N.D. Tex. 2004) (holding that plaintiff's claim of privilege to all documents "because they were made by or sent to in-house or outside counsel" was improper "categorical approach to the attorney-client privilege"). Accordingly, these general descriptions are not privileged.

Moreover, the privilege does not extend to protect intentionally illegal conduct, such as Empower's, particularly where it is part of defense to a claim and poses substantial risk of harm to the public.⁵ *See* Texas Disciplinary Rules of Professional Conduct 1.05(c)(7) and 1.05(e).

Finally, Empower argues that it alone holds the power to waive the privilege. However, Empower should not be permitted to use the privilege as a sword and shield in litigation where it is suing Ludowig.⁶ See Texas Disciplinary Rules of Professional Conduct 1.05(c)(5)&(6); Texas Disciplinary Rules of Professional Conduct 1.05(d)(2)(ii)-(iii).

In sum, the Court should not seal these communications that identify Empower's illegal conduct, because the statements are not privileged, identify illegal conduct posing a substantial risk to the public, and are key to Ludowig's defenses.

C. Empower's cite to the Protective Order does not establish that records should be sealed

Empower's general reliance on the protective order throughout its Motion to seal documents is misplaced, because the protective order has little to no bearing on this Court's

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⁵ Ludowig also observes that the attorney-client privilege must be narrowly construed as applied to in-house counsel. Otherwise, as Empower seeks to do here, an illegal operation could simply hide behind the privilege to prevent disclosure of knowingly illegal activity that are actually business decisions.

⁶ Notably, Empower has only identified 13 privileged communications in a privilege log it produced on June 19, 2025. The communications at issue here have not been produced and are not on Empower's privilege log, suggesting that Empower is not treating the communications as privileged.

analysis. *See generally*, (Motion.) The standard for moving to seal documents "is far more arduous" than the standard for entering a protective order, and sealing documents only because they are subject to a protective order is an abuse of discretion. *June Medical*, 22 F.4th at 519–21 (remanding to district court where district court bulk sealed documents based on the documents being subject to protective order). Accordingly, Empower's reliance on the Protective Order has no bearing on whether the documents should be sealed.

D. The public's interest in the information outweighs any potential harm to Empower

Empower's remaining argument is the bare assertion that disclosure of the information will harm Empower. This bare assertion is insufficient, as Empower did not undertake the requisite analysis. *Binh Hoa Le v. Exeter Finance Corp.*, 990 F.3d 410, 419–21 (5th Cir. 2021) (denying motion to seal where party made mere conclusory allegations without sealing analysis, particularly since the documents were at issue on summary judgment briefing); *IF G Port Holdings, L.L.C. v. Lake Charles Harbor & Terminal District*, 82 F.5h 402 411–12 (5th Cir. 2023) (conclusory assertion in affidavit that information is "competitively sensitive" insufficient to seal documents).

Further, taken to its logical conclusion, Empower complains that it is worried about additional FDA or regulatory inspections due to the statements. These inspections would check to see if, since April 22, 2025, Empower has brought its operations into compliance, such that it is no longer distributing contaminated medications to the public—*i.e.*, any inspection would be a benefit to the public. Put another way, Empower's Motion tacitly admits it knows it will not pass regulatory inspections. Thus, Empower's Motion in itself is an improper means of seeking to seal its illegal operations that place consumers who receive Empower's contaminated medications in harm's way each day of the next compounding pharmacy outbreak.⁷ The public interest in this

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⁷ See DOJ, New England Compounding Center Pharmacist Sentenced for Role in Nationwide Fungal Meningitis Outbreak, (Jan. 31, 2019), https://www.fda.gov/inspections-compliance-

blatant disregard for laws designed to protect the public far outweighs Empower's interest in being subject to inspections that check whether it follows the law.

V. CONCLUSION

For the reasons above, Defendant Matthew Ludowig respectfully requests the Court deny Empower's Motion to Seal portions of Ludowig's Reply in Support of his Motion for Summary Judgment (Dkt. 155) and Reply in Support of his Motion for Leave (Dkt. 157).

Dated: June 20, 2025. /s/ Aaron A. Wagner

Aaron A. Wagner (attorney-in-charge) Texas Bar No. 24037655 S.D. Texas Bar No. 3813191 Robert G. Wright (*admitted pro hac vice*) KABAT CHAPMAN & OZMER LLP

171 17th Street NW, Suite 1550 Atlanta, Georgia 30363

Tel: (404) 400-7300 Fax: (404) 400-7333

Email: awagner@kcozlaw.com Email: rwright@kcozlaw.com Attorney for Matthew Ludowig

enforcement-and-criminal-investigations/doj-press-releases-involving-fda-oci/january-31-2018-new-england-compounding-center-pharmacist-sentenced-role-nationwide-fungal (compounding pharmacy's distribution of adulterated medications killed over 60 people); DOJ, Dallas Compounding Pharmacy Owner Pleads Guilty in Connection with Misbranded Drug Shipment, (Apr. 24, 2012), https://www.justice.gov/opa/pr/dallas-compounding-pharmacy-owner-pleads-guilty-connection-misbranded-drug-shipment; FDA, FDA's investigation into Guardian's compounded triamcinolone-moxifloxacin drug product (last update July 5, 2018), <a href="https://www.fda.gov/drugs/human-drug-compounding/fdas-investigation-guardians-compounded-triamcinolone-moxifloxacin-drug-compounded-triamcin

product#:~:text=Conclusion,407%20and%20poloxamer%20407%20degradants; Dominic Markwordt, J.D., FDA's Compounding Program, Office of Compliance for Center for Drug Evaluation and Research, at p. 10 (available online at <a href="https://www.fda.gov/media/156360/download#:~:text=Outsourcing%20Facility%20Product%20Reports&text=%E2%80%93%20Section%20503B(b)%20of,the%20previous%20six%2Dmonth%20period

CERTIFICATE OF SERVICE

This certifies that on June 20, 2025, I filed the foregoing **DEFENDANT MATTHEW LUDOWIG'S RESPONSE TO EMPOWER'S MOTION TO SEAL LUDOWIG'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (DKT. 155) AND REPLY IN SUPPORT OF HIS MOTION FOR LEAVE (DKT. 157)** with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

<u>/s/ Aaron A. Wagner</u> Aaron A. Wagner